

Appl. No. : 09/776,232  
Filed : February 2, 2001

### REMARKS

Claims 38-51 and 60-73 are pending in the present application. No amendments have been made by way of this response. Thus, no new matter has been added to the application.

In response to the final Office Action mailed May 18, 2004, Applicants respectfully disagree with all of the rejections set forth in the final Office Action and offer the following remarks. Accordingly, Applicants submit that the application is in condition for allowance.

#### Rejection under 35 U.S.C. § 112, first paragraph -- New Matter

The Office Action has rejected Claims 38-51 and 60-73 under 35 U.S.C. § 112, first paragraph.

Regarding the rejection based upon the term "lymph vessel" in Claims 38 and 45, Applicants direct the Examiner's attention to support in the specification for the amendment. Specifically, Applicants stated in their response filed on August 13, 2003:

Claims 38 and 45 have been amended to include the feature of delivering the antigen directly to a lymph node or lymph vessel. Support for this amendment can be found throughout the specification and in the claims as originally filed, for example, on page 6, lines 19-21; page 59, line 32 to page 60, line 1; page 60, lines 29-32; page 63, lines 26-28; page 67, lines 18-20; page 69, lines 25-31; and the examples.

Applicants again direct the Examiner's attention to the above-referenced passages, specifically to page 6, lines 19-21, which recites: "Preferably, the antigen is delivered directly to the mammal's lymphatic system, such as to the spleen, lymph node or lymph vessel." (Emphasis added.) Additionally, on page 63, lines 26-28 recite: "It is preferable, therefore, that the antigen composition is introduced through a device for local administration to the lymphatic system, e.g. the spleen, a lymph node, or a lymph vessel." (Emphasis added.) Finally, Applicants note that additional support for the term "lymph vessel" can be found in the specification on page 12, lines 7-9, page 67, lines 16-18, and page 70, lines 8-11.

In light of the direct support for the term "lymph vessel" found throughout Applicants' original disclosure, Applicants appreciate the Examiners' acknowledgment that this rejection will be withdrawn.

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Regarding the rejection of the phrase "polypeptide amino acid sequence" in Claims 63 and 68, and the rejection of the phrase "antigen is a lysate of a microorganism or mammalian cell" in Claims 64 and 69, Applicants direct the Examiner's attention to support in the specification for these claims. Specifically, Applicants stated in their response of February 25, 2004:

Support for new Claims 63-73 is found throughout the specification and the original claims, for example, on page 7, line 23 through page 8, line 14, page 25, line 9 through page 26 line 6; page 59, lines 11-16; page 60, lines 8-33; page 61, lines 1-6, page 61, lines 7-27. Thus, no new matter has been added to the application by entering this amendment.

With regard to the phrase "polypeptide amino acid sequence" in claims 63 and 68, Applicants again direct the Examiner's attention to the above-referenced passages, specifically to page 25, lines 13-15, which recites: "Included in such engineered sequences would be polypeptides and epitopes incorporated into some carrier sequence such as an antibody or viral capsid protein." (Emphasis added.)

With regard to the phrase "antigen is a lysate of a microorganism or mammalian cell" in Claims 64 and 69, Applicants again direct the Examiner's attention to the above-referenced passages, specifically to page 25, lines 17-21, which recites: "The epitopic peptide, or the longer polypeptide in which it is contained, may be a component of a microorganism (e.g. a virus, bacterium, protozoan, etc.), or a mammalian cell (e.g. a tumor cell or antigen presenting cell), or lysates, whole or partially purified, of any of the foregoing." (Emphasis added.)

In light of the direct support in Applicants' original disclosure for the phrases "polypeptide amino acid sequence," and "antigen is a lysate of a microorganism or mammalian cell," Applicants appreciate the Examiners' acknowledgment that these rejections will be withdrawn.

Rejection under 35 U.S.C. § 112, second paragraph -- Indefiniteness

The Office Action has rejected Claims 49, 63, 64, 68 and 69 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Regarding the rejection of the Markush group in Claims 63 and 68, Applicants respectfully submit that anyone of skill in the art would recognize that while polypeptides and proteins may, in some instances, have overlapping meanings, a polypeptide and protein are not in all cases the same thing. That is, while all proteins are polypeptides, not all polypeptides are proteins. The term "protein" can carry connotations of completeness, maturity, existence in nature, and associated function. While the term "polypeptide" does not exclude such qualities, it does not necessarily convey such qualities. This difference is explicitly recognized in Applicants' specification, for example, on page 25, lines 11-13, which recites: "[T]he epitopic peptide(s) may reside within a longer polypeptide, whether the complete protein antigen, some segment of it, or some engineered sequence." Thus, a person of skill in the art would recognize that the terms protein and polypeptide are not coextensive. Accordingly, Applicants appreciate the Examiners' acknowledgment that this rejection will be withdrawn.

Regarding the rejection of the term "component" in Claims 49, 64 and 69, Applicants maintain that the term "component" clearly establishes the metes and bounds of the claim, and reiterate their remarks provided in the response filed on February 25, 2004.

The ordinary meaning of the term "component" is "a constituent element, as of a system." Accordingly, Applicants respectfully submit that one skilled in the art having read Applicants' disclosure could readily determine the metes and bounds of the claimed invention. Specifically, a person of skill in the art, reading the phrase "component of a microorganism cell" would recognize that any constituent element of a microorganism cell capable of inducing an immune response would be encompassed by this phrase." (Emphasis added.)

Thus, anyone of skill in the art having read Applicants' disclosure could readily determine the metes and bounds of the claimed invention. Accordingly, Applicants appreciate the Examiners' acknowledgment that this rejection will be withdrawn.

### CONCLUSION

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding final Office Action have been addressed and that the application is in condition for allowance. Accordingly, Applicants request the expeditious allowance of the pending claims.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped

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issues remain, or if any issues require clarification, the Examiner is respectfully requested to call the undersigned to discuss such issues.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: June 14, 2004

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